October 18, 1999

OVERVIEW OF NALED REVISED RISK ASSESSMENT

Introduction

This document summarizes EPA's human health and ecological risk findings and conclusions for the organophosphate pesticide naled, as presented fully in the documents, "Naled Revised HED Risk Assessment for RED (PC Code 034401)," dated October 12, 1999, "EFED's Reregistration Chapter for Naled", dated November 14, 1997, and Naled: Addendum to EFED's Reregistration Chapter dated March 18, 1999. The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments and to better understand the conclusions reached in the assessments. References to relevant sections in the complete documents are provided to allow the reader to find the place in these assessments where a more detailed explanation is provided. This summary was developed in response to comments and requests from the public which indicated that the risk assessments were difficult to understand, that they were too lengthy and that it was not easy to compare the assessments for different chemicals due to the use of different formats.

This risk assessment for naled will soon be followed by an opportunity for public comment on EPA's risk management proposal for this pesticide. The Agency will make the upcoming proposal available to the public by placing it in the Pesticide Docket and posting it on the Internet. Public comments will be invited and welcomed for 60 days.

It has been determined that the organophosphates share a common mechanism of toxicity: the inhibition of cholinesterase levels. As required by FQPA, a cumulative assessment will need to be conducted to evaluate the risk from food, water and non-occupational exposure resulting from all uses of OPs. Currently, the Agency is developing draft methodology needed to conduct such an assessment with guidance/advice provided by the Science Advisory Panel. It is anticipated that this draft methodology will be available in the fall of 1999 for external comment and scientific peer review. Consequently, the risks summarized in this document are only for naled.

Use Profile

- **Insecticide/acaricide:** Registered for use primarily to control adult mosquito and blackfly populations. Naled is also used on a variety of food and feed crops including almonds, beans (dry and succulent), broccoli, Brussels sprouts, cabbage, cauliflower, celery,

collards, cottonseed, cucumbers, eggplant, grapefruit, grapes, hops, kale, lemons, melons, oranges, peaches, peas (succulent), peppers, safflower seed, spinach, strawberries squash, swiss chard, sugarbeets (roots and tops), tangerines, tomatoes, and walnuts. Naled is also registered for use in greenhouses and in pet flea collars.

- **Formulations:** Formulated as liquid ready to use, emulsifiable concentrate, impregnated collar/tag, and soluble concentrate/liquid.

- **Method of Application:** Air and ground equipment, hot plate/hot pan (in greenhouses), and impregnated pet collars.

- **Use Rates:** Agricultural 0.7 - 2.8 lb ai/A; Non-agricultural 0.05 - 0.25 lb ai/A.

- **Annual Poundage**: 700,000 lbs for mosquito/blackfly control; 280,000 lbs. for agricultural uses; 20,000 lbs for pet collars. For mosquito/blackfly control, approximately 98% is used to control mosquitos with 95% of the mosquito use being applied aerially.

- **Registrant:** AMVAC Chemical Corporation (purchased from Valent November 2, 1998)

Human Health Risk Assessment

Naled has as one of its degradates, dichlorvos, another registered organophosphate. This is the only degradate of toxicological concern for naled (food and water). Dichlorvos is included in the naled tolerance expression. Risks from naled derived dichlorvos will be calculated in an aggregate assessment for dichlorvos and will be included in the dichlorvos risk assessment. Because of the common metabolite, the risk assessment for naled can not be considered complete until the assessment for dichlorvos has also been completed.

Acute Dietary (Food) Risk

Acute dietary risk is calculated considering what is eaten in one day (in this instance, the individual who consumed the most) and maximum, or high-end residue values in food. A risk estimate that is less than 100% of the acute Population Adjusted Dose (acute PAD) (the dose at which an individual could be exposed on any given day and no adverse health effects would be expected) does not exceed the Agency's risk concern.

It is possible to estimate a more realistic and more refined estimate of acute dietary exposure by using a probabilistic technique. For each individual, the program uses the consumption values reported by that individual. A residue value is randomly selected from the available data, which can include zeros. The ability to include zeros which represent the proportion of the crop not treated makes the use of a probabilistic technique a powerful tool. By performing these operations over 1000 times, an exposure estimate is obtained, which is then

compared to the acute PAD.

The acute dietary risk (food) for naled does not exceed the Agency's level of concern (i.e., less than 100% of the acute PAD is utilized).

- End point is cholinesterase inhibition in plasma and brain from rat gavage study (NOAEL = 1.0 mg/kg/day).

- Uncertainty factor (UF) of 100 includes 10x for interspecies extrapolation and 10x for intraspecies variability.

- The 10x FQPA safety factor was removed based on a complete toxicology database that indicated no increased sensitivity to infants and children. In prenatal developmental toxicity studies following *in utero* exposure in rats and rabbits and in a pre/postnatal reproduction study in rats, there was no evidence of effects at lower doses compared to maternal animals nor was there evidence of an increase in severity of effects at or below maternally toxic doses.

- The acute PAD is calculated to be 0.01 mg/kg/day derived from a NOAEL of 1.0 mg/kg/day and a UF of 100 that includes 10X for interspecies extrapolation, 10X for intraspecies variation and 1X for FQPA.

- A probabilistic Monte Carlo analysis was conducted for the acute dietary risk assessment. For the most exposed subgroup, Children (1 to 6 years old), 39 percent of the acute PAD is occupied, at the 99.9 percentile of exposure level.

- Residues used in the acute dietary exposure analysis are based on the portion of the tolerance level that can be attributed to naled residues only (that is to say the contribution of dichlorvos residues to the tolerance expression has been removed). Residues of dichlorvos resulting from naled applications will be included in the risk assessment for dichlorvos. All naled residue estimates used in the acute dietary exposure analyses can thus be considered upper-bound estimates because they are based on tolerance levels. The proportion of naled to dichlorvos was estimated using field trial data. Possible residues on food items from the mosquito (widespread) use of naled were not considered in the acute analysis.

- This dietary assessment was also refined by using the following maximum percent of crop treated data. (1% for beans, cottonseed, cucumbers, eggplants, grapefruit, hops, lemons, lettuce, melons, peas, peaches, peppers, pumpkins, rice, spinach, sugarbeets winter squash, tomatoes, and turnips; 2% for almonds and oranges; 3% for tangerines; 4% for walnuts; 5% for grapes; 7% for collards; 10% for broccoli; 11% for cabbage; 18% for celery; 26% for cauliflower; 83% for Brussels sprouts; 100% for Swiss chard, kale, mushrooms, meat, milk, and eggs.)

- On August 2, 1999, the Agency published a FR Notice revoking the meat, milk, poultry and egg tolerances of naled. The revocation of these tolerances have not been accounted for in the acute dietary analysis. This revocation will be included before a final cumulative assessment is completed for naled.

United States Department of Agriculture Pesticide Data Program (USDA-PDP) monitoring data were not used. Naled was measured in the USDA-PDP. However, naled was converted during the analysis to dichlorvos, and was measured and reported as dichlorvos. Therefore, the dichlorvos measurements reported by PDP are the sum of naled and dichlorvos residues, and could have resulted from applications of either naled or dichlorvos.

No comments were submitted to significantly change the preliminary risk assessment. However, the assessment was changed to incorporate the FQPA sections (10x safety factor and a water assessment), and to reflect the use of a Monte Carlo analysis and percent crop treated data for the acute dietary assessment.

Chronic Dietary (Food) Risk

Chronic dietary risk is calculated by using the average consumption values for food and average residue values for those foods over a 70-year lifetime. A risk estimate that is less than 100% of the chronic PAD (the dose at which an individual could be exposed over the course of a lifetime and not expect an adverse health effect) does not exceed the Agency's level of concern.

The chronic dietary risk (food) for naled does not exceed the Agency's level of concern (i.e., less than 100% of the chronic PAD is utilized).

- Endpoint is cholinesterase inhibition in brain from a chronic toxicity/carcinogenicity study in rats. (NOAEL = 0.2 mg/kg/day).

- Uncertainty factor (UF) of 100 includes 10x for interspecies extrapolation and 10x for intraspecies variability.

- The 10x FQPA safety factor was removed based on a complete toxicological database that indicated no increased sensitivity to infants and children.

- The chronic PAD is calculated to be 0.002 mg/kg/day derived from a NOAEL of 0.2 mg/kg/day and a UF of 100 that includes 10X for interspecies extrapolation, 10X for intraspecies variation and 1X for FQPA.

- A refined chronic dietary risk assessment was conducted for naled. For the U.S. population 1.6% of the chronic PAD is occupied. The subgroup most highly exposed,

Children (aged 1-6), occupies 3.2% of the chronic PAD.

- Anticipated residues (ARs) based on field trials were used in the chronic dietary analysis corrected by cooking factors where applicable. This dietary assessment was also refined by using the same percent of crop treated data as in the acute analysis.

- As a result of the mosquito/blackfly control use, it is assumed that any commodity could potentially have naled residues on it as a result of the wide area spraying. Therefore, an anticipated residue value was determined in field trials using a mosquito application and adjusting for 4 percent crop treated for all raw agricultural commodities that do not have naled tolerances. No additional residues were assumed for commodities that have naled tolerances.

- On August 2, 1999, the Agency published a FR Notice revoking the meat, milk, poultry and egg tolerances of naled. The revocation of these tolerances have not been accounted for in the chronic dietary analysis. This revocation will be included before a final cumulative assessment is completed for naled.

No comments were submitted to significantly change the preliminary risk assessment. However, the assessment was changed to incorporate the FQPA sections (10x safety factor and a water assessment), and to reflect the use of a DEEM analysis with percent crop treated data for the chronic dietary assessment.

Drinking Water Dietary Risk

Drinking water exposure to pesticides can occur through groundwater and surface water contamination. EPA considers both acute (one day) and chronic (lifetime) drinking water risks and uses either modeling or actual monitoring data, if available, to estimate those risks. To determine the maximum allowable contribution from water allowed in the diet, EPA first looks at how much of the overall allowable risk is contributed by food and then determines a “drinking water level of comparison” (DWLOC) to ascertain whether modeled or monitoring levels exceed this level.

The drinking water risks estimated for naled do not exceed the Agency’s level of concern.

- Modeling and laboratory data indicate that for naled, degradation is rapid, and thus residues of naled are not likely to leach into ground water.

- The Agency calculated estimated environmental concentrations (EECs) for naled in surface water based on PRZM-EXAMS modeling. This model estimates an upper end potential concentration in surface water. The acute EEC is 12.7 ppb and the chronic EEC is 0.56 ppb for naled in surface water.

- Since acute and chronic dietary exposures (food) to pesticidal residues of naled do not exceed the Agency's levels of concern, the Agency calculated DWLOCs.

- **Acute water risk**: There are no acute concerns for naled in drinking water. The most exposed subgroup is children (1 to 6 years old), with a DWLOC of 61 ppb. The acute surface water EEC (12.7 ppb) is well below the DWLOC and residues of naled are not expected in groundwater.

- **Chronic water risk:** There are no chronic concerns for naled in drinking water. The most exposed subgroup is children (1 to 6 years old), with a DWLOC 19 ppb. The chronic surface water EEC (0.56 ppb) is well below the DWLOC and residues of naled are not expected in groundwater.

- Comments were submitted to the Agency which, when incorporated, would result in lower estimates of surface water concentrations. However, because the risks do not exceed the Agency's level of concern, the model was not rerun at this time. These changes would be done prior to any cumulative risk assessment.

Residential Risk

The residential risk assessment was conducted after the preliminary risk assessment was completed. All residential uses, except pet collars, have been voluntarily canceled by the registrant. However, there are potential post-application residential exposures to adults and toddlers entering treated lawns after aerial application(s) for blackfly control. The calculated risks for blackfly control and pet collars exceed the Agency's level of concern.

Mosquito/Blackfly Control

- Chemical-specific contact and transfer data for mosquito uses are not available. Therefore, the methods and assumptions were taken from the Draft Standard Operating Procedures (SOPs) for Residential Exposure Assessments guidance document. Although the SOPs were initially developed for direct turf applications, the models are used in this assessment to determine if there is a potential concern. Based on the SOPs, it is assumed that 5% of the residues on turf are available for dermal exposure and 20% for oral exposure (eg. for toddler hand-to-mouth) when they are contacted.

- To estimate spray drift for ground-based fogger applications two malathion surrogate studies were used. From these data, it was estimated that 5 percent of the application rate is deposited on turf.

- To calculate deposition from aerial ultra-low volume (ULV) applications, *AgDRIFT* (V 1.03, June 1997), the model that was developed as a result of the efforts of the *Spray*

Drift Task Force (SDTF), was used. From the modeling data, it was estimated that 30 percent of the application rate is deposited on turf.

- Potential dermal exposures to toddlers and adults was assumed to be 2 hours per day while engaged in a high-end exposure activity (playing and rolling on turf). It is also assumed that only shorts (no shirt, shoes or socks) are worn during the 2 hour exposure duration.

- A dermal NOAEL of 1 mg/kg/day was selected in calculating the MOE for dermal exposure from the mosquito/blackfly applications. The short- and intermediate-term MOEs are not of concern for dermal contact for adults (MOE = 97) and toddlers (MOE = 100) following aerial ultra low volume mosquito applications. However, the short- and intermediate-term MOEs are less than 100 (potentially of concern) for dermal contact for adults (MOE = 48) and toddlers (MOE = 51) following aerial ultra low volume blackfly applications.

- The dermal MOEs are likely to be an overestimation based on the use of the dermal NOAEL of 1 mg/kg/day. Based on dermal absorption data on two very similar compounds, dichlorvos and trichlorfon, the existing dermal toxicity study likely overestimates dermal toxicity because of the 20 fold difference between the lowest adverse effect level (LOAEL) and the no adverse effect level (NOAEL).

- Chemical-specific deposition data for both the aerial and ground-based mosquito/blackfly applications and information on application timing (e.g., if applications are restricted to the evening, residue dissipation could be accounted for in the exposure assessment) would likely decrease the risk estimates for these uses.

<u>Pet Collars</u>

There are dermal and inhalation exposure concerns from handling pet flea collars. The exposure includes putting the collar around the neck of the animal as well as petting/playing with the animal. Flea collars containing less than 1.4 grams of naled are not of concern for adult long-term exposure. However, these collars exceed the level of concern for children (MOE = 21 - 74). For products that contain more than 1.4 grams of naled, the risks are a concern for both adults and children (MOE = 10 - 83).

- The long term exposure oral NOAEL of 0.2 mg/kg/day was used in this risk assessment. It is based on brain cholinesterase inhibition at the 2.0 mg/kg/day LOAEL in a chronic rat study.

- The methods and assumptions were taken from the draft Standard Operating Procedures (SOPs) for Residential Exposure Assessments guidance document.

- Since there are no data available, it was assumed that 1 percent of the active ingredient is available for dermal and respiratory exposure from handling flea collars. Exposures were amortized over use time (labeled efficacy of the product is 4-5 months) assuming linear dissipation.

Aggregate Risk

Aggregate risk looks at the combined risk from exposure through food, drinking water, and residential uses of a pesticide. Generally, all risks from these exposures must occupy less than 100 percent of the acute and chronic reference doses to be below the Agency's level of concern.

Dietary risk for food and water are not of concern when aggregated. Because the MOEs for the blackfly use as well as the pet collar use already are a concern individually, the Agency is not aggregating these uses with the dietary risk at this time, since additional exposure will only make this exceedance larger.

Occupational Risk

Workers can be exposed to a pesticide through mixing, loading, or applying the pesticide, and re-entering a treated site. Worker risk is measured by a Margin of Exposure (MOE) which determines how close the occupational exposure comes to the No Observed Adverse Effect Level (NOAEL) taken from animal studies. Generally, MOEs that are greater than 100 do not exceed the Agency's level of concern. For workers entering a treated site, Restricted Entry Intervals (REIs) are calculated to determine the minimum length of time required before workers or others are allowed to re-enter.

- The occupational risk assessment has been updated since the preliminary risk assessment to reflect lower use rates for some uses agreed to earlier by the registrant, removal of certain application methods, and the addition of the assessments for the non-agricultural uses.

- Dermal risks were assessed using a NOAEL of 1.0 mg/kg/day from a 28-day dermal rat study. The dermal study demonstrated a LOAEL of 20 mg/kg/day based on dermal irritation; reduced weight gain; and brain, plasma and RBC cholinesterase inhibition.

- Inhalation risks were assessed using a NOAEL of 0.053 mg/kg/day (or 0.2 µg/L) from a 13-week rat inhalation study. The LOAEL was 1 µg/L based on inhibition of plasma and RBC cholinesterase levels.

- Naled use patterns show that both short and intermediate term exposure is possible, however, these assessments were done together, as one assessment, because the endpoints are the same. Exposure was assumed to be seven days.

Mixer/Loader/Applicator

Agricultural

- Risk estimates were derived from the Pesticide Handlers Exposure Database (PHED) using standard assumptions based on the exposure scenarios and types of equipment anticipated by current labeling.

- The combined dermal and inhalation MOEs for naled are of concern for most of the agricultural use scenarios, even with full PPE and engineering controls (closed mixing/loading and enclosed cabs). The MOEs of concern range from 10 - 85, depending on the scenario. Although, there are exposure scenarios that result in MOEs that are less than 100, the dermal MOEs are likely to be an overestimation based on the use of the dermal NOAEL of 1 mg/kg/day. Based on dermal absorption data on two very similar compounds, dichlorvos and trichlorfon, the existing dermal toxicity study likely overestimates dermal toxicity because of the 20 fold difference between the lowest adverse effect level (LOAEL) and the no adverse effect level (NOAEL).

- The table that follows shows the MOE calculations for agricultural uses. Current naled labels do not require engineering controls. The MOEs shown in the table assume workers use closed mixing systems and enclosed cockpits/cabs. PPE for workers using engineering controls includes long pants, long-sleeved shirts and no gloves (except that chemical resistant gloves are assumed for workers mixing liquids).

- The PPE currently required on labels consists of coveralls over long-sleeved shirt and pants, chemical resistant gloves, chemical resistant footwear plus socks, protective eyewear, chemical resistant headgear for overhead exposure, a respirator, and a chemical resistant apron when cleaning equipment, mixing, or loading.

- The registrant has agreed to phase in the requirement to use closed mixing/loading systems for all naled products, with implementation to be completed by the year 2000. The closed system does not apply for workers handling one gallon or less of product per day. The registrant has previously agreed to require closed cockpit for all aerial applications.

- Although, not included in the table, it is likely that the same person may mix, load, and apply the pesticide for groundboom and airblast applications. In such cases, the risk estimates for these workers would be higher than the individual estimates for mixing/loading and applying that are presented here.

Table 1. Summary of MOE Values for Agricultural Uses of Naled (MOEs <100 are of concern)

Exposure Scenario	Crop Grouping[a]	Total Dermal and Inhalation MOE
Mixer/Loader Exposure		
Mixing All Liquids for Aerial (350 acres treated)	(B)	10
	(D)	14
	(E)	20
	(G)	27
Mixing All Liquids for Groundboom (80 acres treated)	(B)	42
	(D)	63
	(E)	85
	(G)	120
Mixing of Liquids for Airblast (40 acres treated)	(A)	63
	(C)	85
	(F)	210
Applicator Exposure		
Aerial equipment (liquids) (350 acres treated)	(B)	16
	(D)	22
	(E)	35
	(G)	48
Groundboom (liquids) (80 acres treated)	(B)	57
	(D)	82
	(E)	110
	(G)	150
Airblast equipment (40 acres treated)	(A)	27
	(C)	41
	(F)	78
Flagger Exposure		
Liquids (350 acres treated)	(B)	330
	(D)	460
	(E)	640
	(G)	1100

[a]Crop groupings are: (A) almond, peach, max appl rate 2.813 lb a.i./A; (B) broccoli, cabbage, cauliflower, brussels sprouts, kale, collards, eggplant, pepper, melon, squash, walnut (aerial only), max appl. rate 1.875 lb a.i./A; (C) citrus, max appl rate 1.875 lb a.i./A; (D) beans, peas, celery, chard, spinach, seed alfalfa, max appl rate 1.406 lb a.i./A; (E) cotton, strawberry, sugarbeet, hops, seed alfalfa, rangeland, max appl rate 0.938 lb a.i./A; (F) grape, walnut, max appl rate 0.938 lb a.i./A; and (G) safflower, max appl rate 0.703 lb a.i./A.

Greenhouse

- The Agency has estimated exposures of individuals performing hot plate applications in greenhouses. These risks were calculated to be below the level of concern assuming the PPE currently required: coveralls over long-sleeved shirt and pants, chemical resistant gloves, chemical resistant footwear plus socks, protective eyewear, chemical resistant headgear for overhead exposure, a respirator, and a chemical resistant apron when cleaning equipment, mixing, or loading.

- For the greenhouse hand-held fogger application the Agency has no data. The label currently requires that applicators and other handlers wear: coveralls over short-sleeved shirt and short pants, chemical resistant gloves, chemical resistant footwear plus socks, protective eyewear, chemical resistant headgear for overhead exposure, a respirator, and a chemical resistant apron when cleaning equipment, mixing, or loading.

Non-Agricultural (Mosquito/Blackfly)

- The registrant has agreed to phase in the requirement to use closed mixing/loading systems for all naled products, with implementation to be completed by the year 2000. The closed system would not apply for workers handling one gallon or less of product per day.

- The registrant has previously agreed to require closed cockpit for all aerial applications.

- For the ground fogger use, the registrant has agreed to phase in the use of enclosed cabs.

- The PPE currently required on labels consists of coveralls over long-sleeved shirt and pants, chemical resistant gloves, chemical resistant footwear plus socks, protective eyewear, chemical resistant headgear for overhead exposure, a respirator, and a chemical resistant apron when cleaning equipment, mixing, or loading.

- The combined dermal and inhalation MOEs for naled are of concern (< 100) for mixer/loader/applicators when loading/applying liquids for the aerial and ground non-agricultural use scenarios, even with full PPE and engineering controls (closed mixing/loading and enclosed cabs). There are exposure scenarios which result in MOEs that are less than 100. The dermal MOEs are likely to be an overestimation based on the use of the dermal NOAEL of 1 mg/kg/day. Based on dermal absorption data on two very similar compounds, dichlorvos and trichlorfon, the existing dermal toxicity study likely overestimates dermal toxicity because of the 20 fold difference between the lowest adverse effect level (LOAEL) and the no adverse effect level (NOAEL).

- Although, not included in the table, it is likely that in some cases the same person may mix, load, and apply the pesticide for groundboom and airblast applications. In such cases

the risk estimates for these workers would be higher than the individual estimates for mixing/loading and applying that are presented here.

Table 2. Summary of MOE Values for Mosquito/Blackfly Uses of Naled (MOEs <100 are of concern)

Exposure Scenario	Maximum Label Rate (lb ai/A)	Total Dermal and Inhalation MOE
Mixer/Loader Exposure		
Mixing/loading Liquids for Aerial ULV Application (7500 acres treated)	0.05 (mosquito)	18
	0.1 (mosquito)	9
	0.25 (blackfly)	4
Mixing/loading Liquids for Ground based Fogger ULV Application (3000 acres treated)	0.05 (mosquito)	46
	0.1 (mosquito)	23
	0.25 (blackfly)	9
Applicator Exposure		
Aerial ULV applicator (7500 acres treated)	0.05 (mosquito)	30
	0.1 (mosquito)	15
	0.25 (blackfly	6
Ground based Fogger ULV applicator (3000 acres treated)	0.05 (mosquito)	17
	0.1 (mosquito)	8
	0.25 (blackfly	3

Post-Application

Agricultural

- Based on the rapid dissipation of naled dislodgeable foliar residues (DFR), as demonstrated in two grape monitoring trials, new interim REIs have been estimated. The registrant must submit confirmatory data to determine definitive REIs for all crop groups/use sites on which naled is registered for use. The new interim REIs are 2 days for grapes and all other crops with an application rate of 0.938 lb ai/acre and 3 days for crops with a higher application rate. Previously the REIs were 24 hours for all uses. However, the REIs of 2 and 3 days are currently on the naled labels.

Greenhouse

- The Worker Protection Standard establishes generic entry restrictions when vapors are applied in a greenhouse. No entry is permitted (other than entry by pesticide handlers who are trained and equipped with personal protective equipment (PPE) -- including respirators) into the greenhouse until one of the WPS ventilation criteria has been met.

- Naled is a liquid at room temperature and must be heated to form a vapor for even dispersal. It likely condenses back into liquid form as it cools, leaving some residue on greenhouse surfaces, including plant leaves. Since the vapor pressure is approximately 2 x 10^{-4}, it is possible that there is an off-gassing effect from the residue that continues after ventilation clears the remnants of the initial vapor.

- Greenhouse reentry exposure estimates were derived from the dislodgeable foliar residue studies on grapes and should be considered highly conservative. Application rates to grapes are much higher than those for greenhouses. It is also unlikely that greenhouse applications would yield appreciable dislodgeable foliar residues since the heat generated product is in vapor rather than aerosol form. Some of the labels specify to avoid direct application to plants as injury may result. While it is possible that there will be some deposition of naled on foliage due to condensation, the amount that would be deposited would be expected to be much less than that from a high application spray formulation. A reentry interval of approximately 32 hours is required before the target MOE of 100 is reached. The current greenhouse REI on the labels is 24 hours.

Ecological Risk Assessment

Nontarget Terrestrial Animal Risk

- Acute risk to birds and mammals is not a concern as the result of the application rate reduction for almonds from 7.2 to 2.8 lb ai/A. The lower application rate is currently on the labels.

- Although environmental fate data indicate that naled will not persist in the environment (half life is 2 days in the field) there is some potential for chronic risk because many naled uses involve multiple applications at short intervals. However, based upon the reduction in the number of applications and some application rates previously agreed to by the registrant and currently on the labels, chronic risk to birds and mammals is not a major concern.

Nontarget Aquatic Animal Risk

<u>Freshwater</u>

- Acute and chronic risk to freshwater fish is not a concern as a result of the application rate

reduction for almonds from 7.2 to 2.8 lb ai/A. The lower application rate is currently on the labels.

- There is significant potential for acute and some potential for chronic risks to freshwater invertebrates from all major uses of naled. These calculated risk are significantly reduced by including reductions in the rates and number of applications agreed to by the registrant and currently on the labels. Recalculation of the modeled EECs for surface water would also decrease the risk estimates. However, risk estimates for invertebrates would remain a concern.

Estuarine/Marine

- Citrus and mosquito control are the major uses of naled that result in possible estuarine exposures. Acute and chronic risks to estuarine/marine fish are not expected from either the citrus or mosquito use.

- The only risk of concern for estuarine/marine invertebrates is chronic risk from the citrus use. The registrant has reduced the application rate on citrus from 1.87 to 0.94 lb ai/A in Florida to reduce exposure to aquatic organisms. Even with the reduction in the application rate this risk remains a concern.

Summary of Public Comments

The Agency received comments from the registrant addressing naled as well as general comments relating to all OPs from various sources. The Agency reviewed these comments but no substantive revisions were made to the human health risk assessment based on these comments.

Comments submitted to the Agency by the registrant, when incorporated, may result in lower estimates of surface water concentrations and lower estimates of dietary risk. However, since dietary risks do not exceed the Agency's level of concern, the model was not rerun at this time. Prior to doing a cumulative risk assessment including naled, water risk, as well as the dietary risk estimates, will be refined to the greatest extent possible. An addendum was prepared to the ecological risk assessment chapter which estimates the changes in risk resulting from the reductions in the rates and number of applications for certain crops previously agreed to by the registrant and now included on the labels. Avian reproduction studies were submitted to the Agency following preparation of the preliminary risk assessment. The results of these studies and the associated risk estimates are also presented in the addendum.